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BY ELECTRONIC MAIL

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U.S. Environmental Protection Agency
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Re: Petition To Deny Sharda Pyraclostrobin Applications

Dear Mr. Cole:

BASF Corporation ("BASF") hereby petitions the Environmental Protection Agency ("EPA" or the "Agency") to deny the application submitted by Sharda Cropchem Ltd. ("Sharda") to register Sharda Pyraclostrobin Technical ("Technical") and any applications to register end-use products containing that pyraclostrobin technical material.[1] BASF brings this Petition under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as amended, 40 C.F.R. Part 152, the Petition Clause of the First Amendment, and the Administrative Procedure Act, 5 U.S.C. § 555(b).

Sharda's selective method offer to pay failed to cite at least 57 BASF studies necessary to allow EPA registration of the requested Technical product. Absent a complete offer to pay from Sharda, EPA must deny Sharda's application to register the proposed Technical product.

[1] In addition to the application for Technical registration addressed in detail in this Petition, BASF received an offer to pay from Sharda related to one end-use product application. In a June 11, 2021, letter, Sharda identified the end-use product as "Sharda Pyraclostrobin 20% WG." Sharda stated it was using the cite-all option under the selective method of data support and offered to pay for BASF's acute toxicity data. *See* Exhibit M. To the extent Sharda relies on the Technical registration addressed in this Petition, EPA must also deny the end-use application unless and until Sharda offers to pay for all required data. We note that Sharda may not use the formulator's exemption unless it is purchasing "a registered pesticide from *another* producer" (FIFRA Section 3(c)(2)(D); 40 CFR § 152.85. BASF has not supplied and is not supplying Sharda with pyraclostrobin technical and cannot properly be listed as a source by Sharda.

I. BACKGROUND

A. Pyraclostrobin

Pyraclostrobin is a popular fungicide used by farmers and others to control fungal diseases and improve plant health. BASF invented the pyraclostrobin molecule in 1993, and submitted the first application for EPA registration of a pesticide product containing pyraclostrobin in 2000. BASF registered the first pyraclostrobin product with EPA in 2002, and has continued to generate the data necessary to support the continued registration of pyraclostrobin products, expand the approved uses, and support the "plant health" claims that are critical to the product's success. Today, pyraclostrobin is registered for numerous outdoor terrestrial and food uses, including as a seed treatment on corn and soybeans. BASF is the owner and original data submitter of virtually all of the health and environmental data in EPA's files that support the registration of pyraclostrobin products under FIFRA and the Federal Food, Drug, and Cosmetic Act.

B. The Data Required for Registration

A fundamental requirement of FIFRA is that each application for registration must be supported by cited or submitted data sufficient to satisfy the no "unreasonable adverse effects" standard that governs every pesticide registration. FIFRA §§ 3(c)(1)(F), 3(c)(5). A follow-on applicant may cite, and EPA may rely upon, data submitted by another registrant within the preceding 15 years "only if the applicant has made an offer to compensate the original data submitter. . . ." FIFRA § 3(c)(1)(F)(iii) (emphasis added); *see also* 40 C.F.R. § 152.93(b)(3) (a follow-on applicant may cite another company's study without compensation only if "the study was originally submitted to the Agency on or before the date that is 15 years before the date of the application for which it is cited. . .").

The data required to support a particular registration depends on the characteristics of the pesticide active ingredient and the uses sought to be registered. The starting point is 40 C.F.R. Part 158, which sets forth "the minimum data and information EPA typically requires to support an application for pesticide registration. . . ." 40 C.F.R. § 158.1(b). Under Part 158, for instance, EPA requires studies that assess a pesticide product's product performance, toxicology, ecological effects, human exposure, environmental fate, and residue chemistry. *See* 40 C.F.R. Part 158, Subparts E, F, G, K, N, and O. Part 158 indicates whether certain studies are typically required or conditionally required to support registration, based on the proposed uses of the pesticide product. *See, e.g.,* 40 C.F.R. § 158.630(d) (Guidelines 850.2300, 850.1075) (indicating as required certain freshwater fish toxicity studies for all terrestrial use patterns). Data identified as "conditionally required" under Part 158 become "required" when conditions set forth in the test notes are satisfied.

EPA can and frequently does require additional data beyond those specified in Part 158 to support registration of a given pesticide product. As the regulations repeatedly make clear, "FIFRA provides EPA flexibility to require, or not require, data and information for the purposes of making regulatory judgments for pesticide products," and "EPA has the authority to establish or modify data needs . . . on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review." 40 C.F.R. § 158.30(a); *see also id.* § 158.1, § 158.130(a). Ultimately, the data requirements applicable to a given pesticide product include whatever data are needed to allow EPA to adequately evaluate the uses and characteristics of the product and to establish that the product will cause no "unreasonable adverse effects" – the statutory standard that governs every EPA registration decision. *See, e.g.*, 40 C.F.R. § 158.75 ("If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed").

EPA may or may not communicate to registrants a need for certain data to support the continued registration of a given pesticide through various methods, including pre-submission meetings, e-mail, data evaluation records, and registration review documents. Regardless, "it is [each] applicant's obligation under FIFRA to demonstrate that [its] individual product meets the standard under FIFRA and/or FFDCA." 40 C.F.R. § 158.120. That obligation can only be satisfied by data cited or submitted by that applicant.

Whether or not EPA has previously determined particular studies to be necessary to support registration, Sharda's application and this Petition require EPA to make that determination now with respect to the data identified in this Petition. While Sharda's offer to pay does not specify the proposed uses, based on the guideline numbers and studies cited, it appears that Sharda is seeking to register a broad range of outdoor terrestrial uses, including food uses. *See* Letter from J. Wagner, Agent for Sharda International LLC, to BASF Corporation dated September 30, 2020 ("Technical OTP") (attached as Exhibit A) (citing pyraclostrobin residue studies on soybeans, grains, and other crops, and feeding studies on dairy cows and hens). Thus, for purposes of this Petition, BASF must assume that Sharda's proposed labels encompass the broad range of crop and non-crop uses for which pyraclostrobin products have been registered by EPA.

C. Sharda's Selective Method Offer to Pay

On September 30, 2020, Sharda provided BASF an offer to pay under the selective method of data citation, indicating that Sharda is applying for the registration of a product called "Sharda Pyraclostrobin Technical." *See* Exhibit A. The Technical OTP identifies 26 individual BASF studies by Master Record Identification Number ("MRID") that Sharda contends satisfy the generic data requirements applicable to its proposed pyraclostrobin technical product. *See id.*

The offer does not specify the uses for which Sharda seeks registration (although the residue studies Sharda cites indicate that Sharda is seeking to register various terrestrial food uses).[2]

As discussed below, the data requirements and studies cited in the OTP are insufficient to support a technical pyraclostrobin registration. Sharda has failed to cite 57 additional BASF studies that are necessary to allow registration of its technical product. As EPA confirmed when it adopted the original implementing regulations in 1984, EPA "rel[ies] heavily on data submitters to monitor compliance" with the data-citation requirements under FIFRA and to submit petitions where insufficient data have been cited to support an application.[3] In response to such petitions, EPA must ensure that a complete offer to pay has been made that identifies each applicable data requirement and cites all the data necessary to satisfy each requirement and to demonstrate there are no unreasonable adverse effects. *See* 40 C.F.R. §§ 152.90, 152.93(b)(2)(ii). EPA cannot consider BASF's data in support of Sharda's technical application without a complete and legally sufficient offer to pay from Sharda. Furthermore, EPA may not approve any applications to register end-use products containing Sharda's pyraclostrobin technical material until the technical is properly supported by sufficient data.[4]

II. EPA CANNOT PROCESS SHARDA'S APPLICATION BEFORE RESOLVING THE ISSUES PRESENTED IN THIS PETITION

EPA lacks the legal authority under FIFRA to issue a registration to Sharda without first resolving whether Sharda's offer to pay is sufficient, which requires EPA to decide the issues raised in this Petition to Deny. EPA cannot avoid deciding a timely Petition to Deny by issuing a registration and purporting to treat the Petition as a petition to cancel to be decided at some indeterminate future date. FIFRA makes it unlawful for EPA to issue Sharda a registration without first ensuring that Sharda has provided a complete offer to pay for all necessary studies, and such improper reliance on BASF's data would constitute a taking. *See*, *e.g.*, *Ruckelshaus v. Monsanto*, 467 U.S. 986, 1013–14 (1984).

As discussed above, it is a fundamental requirement of FIFRA that each application for registration must be supported by cited or submitted data sufficient to satisfy the no "unreasonable adverse effects" standard that governs every registration. FIFRA § 3(c). Acting on a selective method application requires EPA to decide whether the individual studies cited by the applicant are sufficient to support a finding of no unreasonable adverse effects, or whether additional studies must also be cited. *Id.*; 40 C.F.R. § 152.90. Absent a complete offer to pay

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[2] Sharda's OTP cites to residue studies for the following crop uses: cereal grains, cotton, canola, soybeans, alfalfa, and clover. *See* Exhibit A.

[3] EPA, Pesticide Programs; Pesticide Registration and Classification Procedures; Application Procedures to Ensure Protection of Data Submitters' Rights, 49 Fed. Reg. 30884, 30899 (Aug. 1, 1984); 40 C.F.R. § 152.99(b).

[4] As noted above, BASF received an OTP for an end-use product from Sharda on June 11, 2021. *See* Exhibit M.

compensation for all data that EPA has found to be necessary, EPA lacks the legal authority to issue the registration. FIFRA § 3(c)(1)(F); *Thomas v. Union Carbide,* 473 U.S. 568, 582 (1985) ("It is evident that Congress linked EPA's authority to issue follow-on registrations to the original data submitter's ability to obtain compensation.").

The Agency has confirmed that "EPA cannot lawfully grant an application in the absence of ensuring that an applicant has made all necessary offers to pay . . . ." 79 Fed. Reg. 6819, 6821 (Feb. 5, 2014) (emphasis added). A petition to deny is the designated vehicle for the data owner to be heard on the very question of whether or not the necessary offers to pay have been made, and EPA has made clear it relies heavily on data owners to perform this function. 40 C.F.R. § 152.99; 49 Fed. Reg. at 30899. Due process and FIFRA require that EPA decide this Petition to Deny before EPA can rely on BASF's data to issue a registration to its competitor. *See, e.g.*, *Ruckelshaus*, 467 U.S. at 1011 ("[o]nce . . . others are allowed to use th[e] data" to support registration, the data owner "has lost his property interest in the data."); FIFRA § 3(c)(1)(F)(iii) (EPA may consider data owned by another "only if the applicant has made an offer to compensate"); 40 C.F.R. § 152.105 (EPA "will not begin or continue the review of an application" that lacks a sufficient offer to pay).

By definition, processing a selective method application requires EPA to decide which studies are required to support the registration. It is ultimately Sharda's burden as the applicant to demonstrate that it has offered to pay for all required studies. If not, FIFRA gives EPA just one course of action: "if [EPA] determines that an applicant for registration of a product has acted in any way that deprives an original data submitter of rights under FIFRA section 3(c)(1)(F), the Agency will take steps to deny the application . . . ." 40 C.F.R. § 152.99(c)(3) (emphasis added).

Effectively ignoring petitions to deny by "converting" them to petitions to cancel ignores EPA's fundamental duties and deprives data submitters of their rights under FIFRA. It is inappropriate and EPA has acknowledged as much:

> ensuring that all necessary offers to pay are made is not simply an 'administrative function,' but an obligation that lies at the core of EPA's duty to ensure compliance with the data protection provisions of FIFRA section 3(c)(1)(F) . . . .
>
> While EPA understands the reasoning why some commenters would prefer to engage in those disputes after an application has been granted rather than before, EPA does not believe this is a policy objective reflected in FIFRA . . . .

79 Fed. Reg. at 6822.

Another way to think about this is that, if EPA were ultimately to agree with the points in such a "converted" petition to deny, the only apparent remedy would be to cancel the registration

– at that point after months or years of illegal use. This fails to adequately protect BASF's data rights under FIFRA. *Cheminova v. Griffin*, 182 F. Supp. 2d 68, 76 (D.D.C. 2002) ("as this case illustrates, registration cancellation is not by itself an adequate remedy" . . . as "[i]t is difficult to imagine that Congress intended to permit a manufacturer, even for a limited period of time, to sell pesticides under a registration based on another party's data without compensating that party, and to thus enjoy a "free ride" at a prior registrant's expense.").

Any practice of "converting" petitions to deny into petitions to cancel creates a perverse incentive, encouraging follow-ons to make deficient offers to pay with the knowledge that they can enjoy the benefits of registration for months or years without ever committing to pay compensation for all the required studies. This violates a core statutory purpose of FIFRA. *Cheminova,* 182 F. Supp. 2d at 74 ("the primary purpose of the data-sharing provision [FIFRA § 3(c)(1)(F)(iii)] is to guarantee compensation to original data submitters for the compelled use of their data."); S. Rep. No. 95-334 at 31 (1977) (data compensation was intended to "eliminate the 'free rider'" problem). BASF's data rights would be violated if EPA processes an application and issues a follow-on registration relying on BASF's data without first confirming the sufficiency of the offer to pay, and that violation would continue and be compounded the longer BASF's petition remains unaddressed while Sharda enjoys the full benefits of registration at BASF's expense. We encourage the Agency to abandon this past practice as contrary to EPA's core statutory obligations, which are ultimately designed to protect both data owners and the public.

The only way data submitters' rights can be protected is for EPA to resolve a timely petition to deny, and thus ensure that all required offers to pay have been made, before EPA processes the application and issues a registration in reliance on the data.

III. BASF'S RIGHT TO FILE THIS PETITION

BASF is entitled to file this Petition pursuant to FIFRA § 3(c)(1)(F), and EPA's regulations at 40 C.F.R. Part 152, Subpart E ("Procedures to Ensure Protection of Data Submitters' Rights"), including 40 C.F.R. § 152.99. BASF is a current registrant of pyraclostrobin and the original submitter of the data that support pyraclostrobin registrations under FIFRA. As an original data submitter of studies that satisfy data requirements for pyraclostrobin, that Sharda has failed to satisfy, and having received an insufficient offer to pay data compensation from Sharda, BASF is entitled to submit this Petition requesting that EPA deny Sharda's application. 40 C.F.R. § 152.99(a)(2)(i). BASF's Petition is timely. *See* 40 C.F.R. § 152.99(b)(1).

In addition to a data submitter's specific rights under 40 C.F.R. § 152.99, EPA has recognized its obligation to consider petitions to deny pursuant to the Petition Clause of the First Amendment to the United States Constitution. *See, e.g.*, Letter from J. Jones, Director, Registration Division, Office of Pesticide Programs, EPA, to J. Wright and J. Liss (June 13,

2000) (recognizing the right to petition to deny application under the First Amendment of the Constitution under FIFRA). BASF is also entitled to petition EPA under the Administrative Procedure Act ("APA"), 5 U.S.C. § 555(b); *see also Block v. Sec. & Exch. Comm'n*, 50 F.3d 1078, 1085 (D.C. Cir. 1995) (Section 555(b) of the APA "is universally understood to establish the right of an interested person to participate in an on-going agency proceeding").

IV. ARGUMENT

Sharda failed to identify numerous data requirements applicable to a pyraclostrobin technical registration, and failed to cite at least 57 BASF studies required to satisfy those requirements. These studies are identified as Items 1-57 in Exhibit B (Study List) hereto.[5] The missing data are discussed by study type in the following six sections.

A. Subpart E – Product Performance and Plant Health Data

47734201 Data Supporting Plant Health Claims for Headline Fungicide (EPA Reg. No. 7969-186)

47747201 Supplement to Data Supporting Plant Health Claims for Headline Fungicide: (EPA Reg. No. 7969-186) (MRID 47734201)

Each application for a pesticide registration must be supported by data sufficient to demonstrate to EPA that the proposed product will cause no "unreasonable adverse effects on the environment." FIFRA § 3(c)(5). The statute defines "unreasonable adverse effects" to mean "unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide...." FIFRA § 2(bb)(1). This "risk/benefit" standard also requires each applicant to demonstrate that the product performs its claimed and intended function without unreasonable risk. This standard governs all applications, including Sharda's pyraclostrobin applications here.

Accordingly, each registrant is required to generate and retain in its files "efficacy" or "product performance" data sufficient to establish that the product performs as intended and as the registrant claims on product labeling. 40 CFR § 158.400(e)(1). Registrants are required to submit these product performance data to EPA upon request. *Id.; see also* Exhibit C (Declaration of Amber M. Shirley, PhD.) at ¶ 15. EPA has made clear the circumstances in which it expects to require the submission of product performance data. These circumstances include where a lack of efficacy "has been reported" or where EPA has "reason to suspect" the

[5] This Petition is limited to studies submitted within 15 years of Sharda's applications, which are assumed to be the same date as its offers to pay, September 30, 2020 (technical) and June 11, 2021 (end-use). *See* 40 C.F.R. § 152.93(b); Ex. A; Ex. M. If Sharda's applications were submitted before those dates, BASF reserves the right to supplement this Petition to add additional studies.

product may not be effective in any respect. *See* Exhibit D (EPA Product Performance Test Guidelines) at 3.

Those very circumstances arose for pyraclostrobin concerning plant health data. Pyraclostrobin is unique among strobilurin fungicides in that, in addition to its pesticidal properties, it has secondary beneficial effects for plants known as "plant health benefits." *See* Exhibit C ¶ 6. Upon discovering these properties, BASF requested and EPA approved adding "plant health" claims to its end-use pyraclostrobin product label. *See* Exhibit C ¶¶ 9-12.

Shortly after adding these claims to its labels, however, 62 of the nation's leading university professors of agriculture wrote a detailed letter to EPA calling into question the plant health benefits claims asserted on the label and alleging potential environmental risks from allowing its continued use for that purpose. *See* Exhibit C-7. In response to these reports and concerns, EPA explicitly required BASF to submit the product performance data establishing pyraclostrobin's plant health benefits. *See* Exhibit C ¶ 14; Exhibit C-8. Specifically, EPA unambiguously instructed: "[a]s we discussed prior, please send efficacy data supporting these Headline claims by 3/31/09 (will not be a fast track amendment)." *See* Exhibit C-8. The politeness of EPA's request has no effect on the data's necessity to maintaining the registration. In this regard, EPA's own guidance regarding the requirement to submit product performance data uses the terms "request" and "require" interchangeably. *See e.g.,* Exhibit D. In any case, EPA made clear through several conversations with BASF, that if did not submit sufficient plant health data justifying the claims for each crop use, it would not be allowed to include such claims on pyraclostrobin product labels. *See* Exhibit C ¶ 15.

BASF expended significant resources to generate the data necessary to demonstrate the plant health benefits of pyraclostrobin and submitted those data at EPA's request as **MRIDs 47734201** and **47747201**. *See* Exhibit C ¶ 16. To develop these submissions, BASF conducted over 6,000 trials across the country, applying pyraclostrobin on various crops, at various stages of growth, and under a wide range of agronomic and climate conditions. *Id.* Large numbers of trials were necessary to obtain statistically significant data to establish yield and plant health benefits, through variations in the timing, mixture, and quantity of product application, among other things.

EPA accepted these submissions and continues to rely upon them to support plant health claims on all pyraclostrobin products. *See* Exhibit C ¶ 17; Exhibit C-9. These data, and EPA's requirement of its submission, are specific to the characteristics and effects of the generic pyraclostrobin molecule, not a particular formulation or end-use product. As such, the resulting submissions broadly support all pyraclostrobin registrations, including Sharda's.

A panel of three independent Arbitrators appointed under the FIFRA arbitration rules determined that EPA required these data in a publicly-available decision. They in turn ordered the data citer to pay compensation for the data under FIFRA. *See* Exhibit C-10. EPA must

ensure that these requirements are applied evenhandedly and require that Sharda make a legally sufficient offer to pay encompassing these data, or it must deny Sharda's application.

B. Subpart F – Toxicology

48830601	A 28-Day Oral (Dietary) Natural Killer Cell Immunotoxicity Study of BAS 500 F in Female B6C3F1 Mice
48830602	A 28-Day Oral (Dietary) Antibody Forming Cell Immunotoxicity Study of BAS 500 F in Female B6C3F1 Mice
48830603	A 28-Day Oral (Dietary) Antibody Forming Cell Immunotoxicity Study of BAS 500 F in Female B6C3F1 Mice
49459611	BASF 500 F (Pyraclostrobin) Repeated dose 28-day inhalation toxicity study with recovery period in Wistar rats, aerosol exposure

Sharda has failed to cite four BASF toxicology submissions, each of which is required for registration. First, Sharda failed to cite a repeated dose 28-day inhalation toxicity study with a recovery period in Wistar rats, aerosol exposure (**MRID 49459611**). EPA specifically concluded that this study was "acceptable" and "satisfied the guideline requirement for an inhalation toxicity study (OCSPP 870.3465)." EPA DER (Feb. 4, 2015). *See* 40 C.F.R § 158.500(d). EPA likewise relied on the study for that guideline requirement in its Human Health Draft Risk Assessment as part of the Pyraclostrobin Registration Review in 2019.[6]

Sharda also failed to cite three studies (**MRIDs 48830601, 48830602,** and **48830603**) submitted to satisfy the immunotoxicity data requirement under 40 C.F.R § 158.500(b) (Guideline 870.7800). The first (MRID 48830601), was relied upon by EPA as part of its Human Health Draft Risk Assessment as part of the Pyraclostrobin Registration Review in 2019.[7] These toxicology studies are required to support Sharda's requested pyraclostrobin registrations.

[6] EPA, Pyraclostrobin: Human Health Draft Risk Assessment *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2014-0051-0024
[7] *Id.*

C. Subpart G – Ecological Effects

1. Aquatic Invertebrate Toxicity Data

47924315	Acute Toxicity of BAS 703 02 F to Daphnia magna Straus in a 48 Hour Static Test
47924213	Acute Toxicity of BAS 703 01 F to Daphnia magna Straus in a 48 Hour Static Test
49459608	Acute toxicity of Reg. No. 340266 (Metabolite of BAS 500 F) to Daphnia magna Straus in a 48 hour static test
49302901	BAS 500 F: Life-Cycle Toxicity Test of the Saltwater Mysid, Americamysis bahia, Conducted Under Flow-Through Test Conditions

Acute toxicity data for freshwater invertebrates (Guideline 850.1010) are expressly "required" for all terrestrial and residential outdoor uses in order to assess the hazard a chemical may present in the aquatic environment. *See* 40 C.F.R. § 158.630(d). Sharda has not listed any studies in their OTP that relate to acute toxicity for freshwater invertebrates. *See* Exhibit A. Sharda failed to cite three BASF studies required to satisfy this data requirement. *See id.* These studies assess pyraclostrobin's and pyraclostrobin metabolites' potential acute toxicity effects on the Daphnia magna Straus using a combination product of fluxapyroxad and pyraclostrobin. (**MRIDs 47924315** and **47924213**). Sharda may or may not seek to register this specific combination product, but the requested registration will allow Sharda's customers to use Sharda's technical product, including in such combinations. EPA required the studies to fully characterize pyraclostrobin's potential acute toxicity effects on freshwater invertebrate populations.

Sharda implicitly acknowledges this by citing *other* studies that were conducted on combination products in its Technical OTP, including the combination used in these studies. *See e.g.* Exhibit A (MRID 47924212).

Sharda also failed to cite a study responsive to Guideline 850.1010 conducted on pyraclostrobin. In 2014, EPA requested in its Preliminary Work Plan evidence for the argument that a pyraclostrobin metabolite (BAS 500-3) is less toxic to particular flora and fauna, including Daphnia magna. *See* Exhibit E. In response, BASF submitted **MRID 49459608**.

Chronic toxicity data (Guideline 850.1350) for saltwater invertebrates is "conditionally required" for all terrestrial and residential outdoor uses in order to assess the hazard a chemical may present in the aquatic environment. *See* 40 C.F.R. § 158.630(d). In response to EPA's request for additional information during registration review about chronic mysid toxicity to

cover Guidelines 850.1350 (Mysid Chronic Toxicity Test) and 850.1000 (Background and Special Considerations-Tests with Aquatic and Sediment-Dwelling Fauna and Aquatic Microcosms), BASF submitted an extensive study. (**MRID 49302901**). *See* Exhibit N; Exhibit O. EPA accepted this study and did not require further data in its October 2015 DCI.

Sharda has failed to cite these four studies and has thus failed to satisfy the Subpart G requirements for a technical pyraclostrobin registration.

2. Freshwater Fish Acute Toxicity Data

47924314	BAS 703 02 F: Acute Toxicity Study in the Rainbow Trout (Oncorhynchus mykiss)
49459609	Reg.No. 340266 (Metabolite BF 500-3 of BAS 500 F) Acute Toxicity Study on the Rainbow Trout (Oncorhynchus mykiss) in Static System over 96 hours
49207302	BAS 500 F - Acute Toxicity Study on the Bluegill (Lepomis macrochirus RAF.) in a Static System (96 Hours)
49604101	BAS 500 (Pyraclostrobin) Acute Toxicity Study in the Fathead Minnow (Pimephales promelas)
49604102	BAS 500 00 F Acute Toxicity Study in the Rainbow Trout (Oncorhynchus mykiss)

Acute toxicity data for freshwater fish (Guideline 850.1075) are expressly "required" for all terrestrial and residential outdoor uses in order to assess the hazard a chemical may present to non-target organisms. *See* 40 C.F.R. § 158.630(d). Sharda cited only MRID 47924212. Sharda failed to cite five additional BASF studies required to satisfy this data requirement. These studies assess the potential acute toxicity effects of pyraclostrobin on the fathead minnow, bluegill, and rainbow trout.

BASF submitted two required studies on the effect of the combination product of fluxapyroxad and pyraclostrobin on March 26, 2010 in rainbow trout. (**MRIDs 47924314**, and 47924212). Sharda cited only one (MRID 47924212). EPA also requested in its Preliminary Work Plan that BASF provide data showing that pyraclostrobin metabolite (BAS 500-3) is less toxic to rainbow trout to which BASF submitted **MRID 49459609** in response. EPA accepted BASF's data and argument, as evidenced by the 2015 DCI that did not require this study.

In 2013, EFED requested an additional fish toxicity study. BASF submitted a study report on acute toxicity on the bluegill fish as well as rationale to address EPA's identified data

gap in Guideline 850.1075 as part of registration review. (**MRID 49207302**). EPA accepted this study and rationale, and no further data were required by EPA in its subsequent DCI.

Finally, EPA also requested additional data regarding acute toxicity in the fathead minnow and rainbow trout. *See* Exhibit F. On March 31, 2015, BASF submitted two studies in response to EPA's request. (**MRIDs 49604101 and 49604102**). Both studies were accepted, and no further data were required in subsequent DCIs.

Without citing these five studies, Sharda has failed to satisfy the Subpart G requirements for a pyraclostrobin registration.

3. Endangered Species Data

46513301 Pyraclostrobin: An Assessment of Risk to Endangered Species of Mammals in Golf Course Turf and Ornamentals

BASF submitted a study (MRID 46373001) analyzing exposure to endangered species to support pyraclostrobin product labeling in September 2004. That study is outside the compensable period and thus is not included in this Petition. However, eight months later, on March 9, 2005, in response to an EFED memo identifying concerns of exposure to endangered species, BASF submitted a second study. **(MRID 46513301)**. Sharda failed to cite this necessary study.

4. Terrestrial and Aquatic Plants Data

47924321 BAS 703 02 F: A Toxicity Test to Determine the Effects of the Test Substance on Seedling Emergence of Ten Species of Plants

49459607 Effect of BF 500-3 (Reg. No. 340266, Metabolite of BAS 500 F) on the Growth of the Green Alga Pseudokirchneriella subcapitata

On March 26, 2010, BASF submitted two studies related to non-target area phytotoxicity, corresponding to EPA Guidelines 850.4100 and 850.4150. Sharda cites the first, MRID 47924320, which tested the effects of pyraclostrobin and fluxapyroxad on the vegetative vigor of ten plant species. Sharda incorrectly describes the guidelines as covering both vegetative vigor as well as seedling emergence data requirements. *See* Exhibit A (using the old guideline number, 850.4250, and titling it "Effects on Non-Target Plants – Seed Germination & Vegetative Vigor). Seedling emergence is a separate data requirement. BASF submitted **MRID 47924321,** which tested the effects on seedling emergence of the same combination substance. Both guidelines are required for terrestrial uses, which Sharda appears to be seeking based on the uses discernable from its Technical OTP. BASF also submitted a study on green alga, looking only at pyraclostrobin, "Effect of BF 500-3 (Reg. No. 340266, Metabolite of BAS 500 F) on the Growth of the Green Alga Pseudokirchneriella subcapitata" on September 29, 2014 (**MRID 49459607**).

Sharda failed to cite either of these studies and thus has not satisfied the Subpart G requirements for pyraclostrobin registration.

5. Pollinator Studies

List of 14 studies provided in Exhibit B at pages 2-5.

Subpart G establishes basic minimum data requirements related to a pesticide's effects on pollinators. *See* 40 C.F.R § 158.630(d) (requiring Guideline 850.3020 "Honeybee acute contact toxicity," and conditionally requiring Guidelines 850.3030 "Honey bee toxicity of residues on foliage" and 850.3040 "Field testing for pollinators"). As is often the case, extensive additional pollinator data were required to support registration for pyraclostrobin. EPA often explicitly requires additional honey bee toxicity and field trial data. Sharda failed to list 14 such studies submitted by BASF in its OTP. *See* Exhibit A.

BASF submitted several acute contact studies corresponding to Guideline 850.3020. Sharda cited three, MRIDs 47924215, 49763117, and 49763712, but failed to cite two others, including one testing a combination, **MRID 47445001**, and one testing pyraclostrobin alone, **MRID 49381101**. Likewise, BASF submitted **MRID 48470201**, a semi-field test of effects on bee brood development corresponding to Guideline 850.3040, on a combination product. That study, along with an assessment of side effects, **MRID 48470202**, was submitted to support an EFED risk assessment for use of that combination product. These acute toxicity data are relevant to the pollinator risks associated with a pyraclostrobin-only product, as combined exposures may occur from tank mixing and supplemental applications of individual products. Sharda failed to include these required studies in its Technical OTP.

Sharda likewise failed to cite **MRID 49459602**, a bee brood study testing products containing pyraclostrobin to support additional food crop and seed treatment uses. Sharda also failed to offer to pay for **MRID 48475901** and **MRID 48812702**, which looked at effects on honeybee brood development from combination products. As discussed above, Sharda may or may not ultimately market these as specific combination products, but many of its customers may use Sharda's technical product in such combinations. Combination data are critical to assessing potential aggregate toxicity. These data must therefore be included in Sharda's offer to pay.

Sharda also failed to cite to two studies submitted in 2012 in response to concerns and uncertainties brought to EPA by commercial beekeepers about the effects of pyraclostrobin and boscalid on queen development. *See* Exhibit G. In response, BASF submitted a package of studies, including **MRIDs 49009303** and **49009304**. Relying on these studies, EPA concluded that "neither boscalid nor pyraclostrobin residues are detected in royal jelly" and that the

combination product "does not appear to affect honeybee queen development." *Id.* Sharda has failed to include either study in its Technical OTP.

Sharda also neglected to cite several studies that were submitted in response to specific EPA requests. In June 2014, EPA initiated registration review for pyraclostrobin and the resulting Preliminary Work Plan outlined various pollinator data needs, including many non-guideline studies. *See* Exhibit H ("Generic DCI"). EPA then issued a Generic Data Call-In confirming the need for additional studies related to field testing (Guideline 850.3040) and non-guideline studies on honeybee adult acute toxicity, honeybee adult chronic toxicity, honeybee larval acute toxicity, honeybee larval chronic toxicity, and residues in pollen and nectar. *See id.* EPA also issued a Specific Data Call-In asking for semi-field testing on pyraclostrobin and additional foliage residue data (Guideline 850.3030). *See* Exhibit I ("Specific DCI"). BASF generated voluminous data regarding pyraclostrobin's effects on pollinators in response to both DCIs. It submitted numerous studies to satisfy the DCIs, many of which Sharda failed to cite. *See* Exhibit B (**MRIDs 49459604, 49459605, 49459606, 49381102, and 49525001**).

More broadly, given the inherent difficulty in generating pollinator field data, EPA has recognized that it relies on a body of pollinator studies as a whole, even if individual studies may be classified as supplemental, to satisfy pollinator data requirements and support a registration. *See* Exhibit J. Sharda must include these additional pollinator studies in an offer-to-pay, and until it does so, its applications are deficient and must be denied.

D. Subpart K – Human Exposure

46788501	Dissipation of Dislodgeable Foliar Residues from BAS 500 00 F Treated Corn
46788502	Determination of Dermal and Inhalation Exposure to Pyraclostrobin to Reentry Workers in Illinois During Corn Detasseling and Validation of BASF Analytical Method D0507
46788503	Pyraclostrobin: Exposure Assessment for Workers Conducting Agricultural Activities in Seed Corn Fields Following Application
47038201	Submission of Completed Human Research for EPA Review for BASF Study Number 211945: Determination of Dermal and Inhalation Exposure to Pyraclostrobin to Reentry Workers in Illinois During Corn Detasseling and Validation of BASF Analytical Method D0507

EPA requires human exposure data to evaluate possible effects on pesticide applicators as well as to evaluate other post-application exposures. *See* 40 C.F.R §§ 158.1020(d) and 158.1070(d). In 2006, BASF submitted two studies as part of a request to reduce the restricted

entry interval ("REI") for pyraclostrobin (**MRIDs 46788501** and **46788503**). These ultimately supported EPA's decision to shorten the worker re-entry interval ("REI") from 7 days to 12 hours. To the extent Sharda relies on this work by including a 12-hour REI on its labels it must cite these two studies.

At the same time BASF submitted the above studies, it also submitted a dermal and inhalation exposure study, **MRID 46788502**, meeting study post-application exposure guidelines 875.2400 and 875.2500. In concert with this data submission to EPA, BASF was required submit its completed research to the Human Studies Review Board ("HSRB"). The HSRB is an advisory committee established by rule, that reviews proposals for and completed research involving human participants. *See* 71 Fed. Reg. 6168 (Feb. 6, 2006). The Rule was further revised in 2013 to strengthen requirements for studies and data submitted by third parties — including pesticide companies submitting pesticide research involving human participants. *See* 78 Fed. Reg. 10538 (Feb. 14, 2013). This required submission, was assigned an MRID and is required for registration. *See* Exhibit B (**MRID 47038201**).

E. Subpart N – Environmental Fate

48037314	Comparison of Pyraclostrobin (BAS 500 F) Field Soil Dissipation Endpoints from North American Trials with EC, WG, and CS Formulations
49881709	Rationale for Citation of Environmental Fate and Ecotoxicology Data in Support of the Registration of a Solid Fungicide Applied In-Furrow to Terrestrial Field Crops
50088701	Validation of BASF Method D1508/01: Analytical Method for the Determination of residues of Pyraclostrobin metabolite, BF 500-3 (Reg.No.340266) in Surface and Drinking Water
50088705	Independent Laboratory Validation of BASF Method L0182/02: "Determination of BAS 500 F (Pyraclostrobin) and Its Metabolites BF 500-5 (Reg. No. 298327), BF 500-12 (Reg. No. 412053), BF 500-11 (Reg. No. 411847), BF 500-13 (Reg. No. 412785), BF 500-14 (Reg. No. 413038) and BF 500-15 (Reg. No. 377613) in ground- and surface- water by LC/MS/MS"
50412401	Anaerobic Aquatic Metabolism of Carbon 14-BAS 500 F: Final Report

BASF submitted three studies supporting the environmental fate analysis for terrestrial field crops. Based upon the limited information available to BASF, Sharda's applications include field crop uses and therefore must provide an offer to pay which includes these studies.

The first, **MRID 48037314**, assessed various pyraclostrobin formulations and compared the resulting soil dissipation. It was submitted as a follow-up to a March 25, 2009 meeting between BASF and EPA's Environmental Fate and Effects Division ("EFED") in which BASF proposed a waiver from further dissipation studies because the formulation does not influence the resulting dissipation of the compound. MRID 48037314 analyzes the dissipation of various formulations, including a wettable granule ("WG"), the same formulation as Sharda's end-use product – Pyraclostrobin 20% WG. In its review of the submission, EPA likewise concluded, "formulation was not an important factor influencing field dissipation of pyraclostrobin." *See* Exhibit K. Sharda's end-use product, as well as the various formulations its customers may employ from the technical product, are supported by these data and EPA's conclusion.

Sharda's Technical OTP also fails to include two submissions validating analytical methods for the dissipation of surface water required under Guideline 835.6100. *See* Ex. B (**MRIDs 50088701** and **50088705**). Sharda does cite two separate analytical methods submitted at the same time (MRIDs 50088704 and 50088706), but all four studies are required to capture the full suite of potential degradates.

Sharda further failed to cite **MRIDs 49881709** and **50412401**. Part 158, Subpart N, broadly requires degradation, metabolism, mobility, dissipation, and groundwater monitoring studies as part of EPA's environmental fate analysis for terrestrial field crops. In June 2016, BASF provided EPA with a submission explaining its rationale for submitting required data, including environmental fate data (**MRID 49881709**), in support of a registration for in-furrow fungicide application to terrestrial field crops. As stated above, based upon the limited information available to BASF, Sharda is seeking terrestrial field crop uses and thus must include this additional submission in its Technical OTP. In 2017, in response to a data call-in, BASF submitted an anaerobic aquatic metabolism study required by EPA (**MRID 50412401**). This study was necessary to maintain the pyraclostrobin registration and Sharda must include this submission in its Technical OTP.

F. Subpart O – Residue Chemistry

See list of 16 studies provided in Exhibit B at pages 6-8.

Finally, EPA requires residue chemistry studies, which are used to estimate the exposure of the general population to pesticide residues in agricultural commodities. 40 C.F.R. 158.1400. EPA requires an applicant applying to register a pesticide for a food use to demonstrate to EPA a "reasonable certainty that no harm will result" from dietary and other human exposures to pesticide residue. 21 U.S.C. § 346a(b)(2)(A)(ii); FIFRA § 2(bb)(1). A pesticide cannot be registered for a food use until EPA has established a tolerance, after considering a substantial amount of residue data. *See e.g.,* Guidelines 860.1000. Extensive data are necessary to demonstrate to EPA that a given pesticide product meets these safety standards and can be registered. *See* FIFRA §§ 3(c)(1)(F), 3(c)(5), (7).

1. Magnitude of residue

EPA requires magnitude of the residue data to support registration of food uses, including crop field trials and data on the nature and level of residues in processed food and feed. *See* 40 C.F.R. §§ 158.1410(b), (d), (e)(15) (Guidelines 860.1500, 860.1520). To satisfy this requirement, BASF submitted magnitude of residue studies for residues of pyraclostrobin for a wide variety of uses including soybeans, mustard greens, cucurbits, clover, canola, sunflowers, strawberries, berries, dry peas and lentils, grapes, stone fruit, cotton (including processed cotton fractions), cherries, plums, peaches, cereal grains and sorghum following seed treatment, sweet corn, field corn, forage corn, wheat, and tomatoes. Sharda cites only a handful of studies relating to cotton, canola, cereal grain seed treatment, alfalfa, soybean, wheat, rice, corn processed fractions; sorghum processed fractions following seed treatment, and clover. *See* Exhibit A (citing MRIDs 46685901, 46925301, 47470203, 47584401, 47774701, 47774702, 49521204, 46685902 and 47511901).

For many of the uses it did cite, Sharda only cited a subset of the required data for a particular crop. For example, Sharda cited to MRID 47511901, a magnitude of the residue study of residues in wheat, rice, and corn processed fractions. Yet, Sharda did not cite **MRIDs 47774601** and **47774602,** which assessed residues of pyraclostrobin in sweet corn and field corn, and wheat agricultural commodities, respectively. Likewise, Sharda did not cite a residue in field corn forage study (**MRID 48037315**).[8] Sharda must cite these studies to enable these uses to the extent it seeks to register products that include such crop uses on their labels.

Sharda's OTP also fails to include residue data supporting uses on mustard greens, cucurbits, sunflowers, strawberries, berries, dry peas and lentils, grapes, stone fruit, cherries, plums, peaches, and tomatoes (**MRIDs 46330001, 46512002, 46512003, 46588101, 46637701, 46638802, 46665504, 46665505, 46665506, 47470201, and 48049201**). EPA's guidelines and regulations provide that each of these studies is necessary in order to establish safe tolerances and residues of pyraclostrobin on these food uses. Despite these regulatory requirements, Sharda has failed to include these magnitude of the residue studies in its offer to pay. To the extent Sharda seeks to register a product that allows for any of these terrestrial crop uses, it must offer

[8] On March 25, 2009, EPA and BASF met regarding proposed concepts for use of pyraclostrobin in field corn. BASF agreed to generate data for field corn forage as part of its proposed "early spray" formulation for control of early season diseases in field corn. It further agreed to submit a wash-off study to determine the release rate of pyraclostrobin from the encapsulated material in soil, as well as a study assessing the amount of pyraclostrobin that washes off the plant foliage and into the soil. *See* Exhibit L. In response to EPA requirements, BASF submitted (MRIDs 48037313 and 48037315). Upon review, EFED stated that the purpose for the studies was to "demonstrate that formulation type is not an important factor influencing the field dissipation." *See* Exhibit K at 9.

to pay for these BASF studies. Without a valid offer to pay, EPA must either limit the registration accordingly or deny Sharda's applications.

2. Analytical Method

BASF submitted four other residue chemistry studies that are required to register a pyraclostrobin product. First, BASF conducted a residue analytical method required under Guideline 860.1340. *See* Ex. B (**MRID 47284902**). The study was prepared to develop and validate an analytical method for determining pyraclostrobin in plant materials. Sharda's OTP includes the study for determining pyraclostrobin in animal tissue (MRID 47938901) but failed to cite this plant study. To the extent Sharda intends to register products that allow in-furrow uses, it must include this study in its Technical OTP.

3. Nature of the Residue

Finally, BASF submitted a rotational crop study, which is conditionally required under Guideline 860.1850 (**MRID 46469501**). Such studies are required by the Agency when, as is the case here, "it is reasonably foreseeable that a food or feed crop could be subsequently planted on the site of pesticide application after harvest or failure of the treated crop." 40 CFR § 158.1410(e) (Test Note 7). Sharda must cite this study as part of its application to register a technical pyraclostrobin product and must therefore include it in a valid offer to pay.

* * * *

As set forth above, Sharda failed to cite at least 57 BASF studies required to support its proposed pyraclostrobin registration. Accordingly, BASF respectfully requests that EPA deny Sharda's applications pyraclostrobin registration, unless and until Sharda provides BASF with a valid offer to pay for the studies identified in Exhibit B.

In filing this Petition, BASF does not waive any of the rights available to it in any forum to seek further relief under FIFRA, the Administrative Procedure Act, or any other source of law. Thank you for your consideration of this submission.

Respectfully submitted,

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Matthew D. Schneider
Counsel for BASF Corporation

Enclosures: Exhibits A through O

cc: Ms. Nora Stoner, EPA, Regulatory Services Branch
James M. Wagner, Sharda Agent
Lindsay Roe, EPA, Fungicide Product Manager
Cynthia Giles-Parker, EPA, Fungicide Branch Chief

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 17th day of August, 2021, a true and correct copy of the foregoing Petition with Exhibits, was served upon the following by e-mail:

Mr. Joseph E. Cole
Associate General Counsel
Office of the General Counsel
U.S. Environmental Protection Agency

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Index of Exhibits Submitted in Support of
BASF's Petition to Deny Sharda's Pyraclostrobin Applications

Exhibit A	Sharda Selective Offer to Pay Letter to BASF, dated September 30, 2020
Exhibit B	Study List, dated August 17, 2021
Exhibit C	Declaration of Amber M. Shirley, PhD., dated July 27, 2021
Exhibit C-1	Curriculum Vitae of Amber M. Shirley, PhD.
Exhibit C-2	E-mail from BASF to EPA, dated February 22, 2006
Exhibit C-3	E-mail from BASF to EPA, dated October 24, 2007
Exhibit C-4	Letter from BASF to EPA re Proposed Labeling for Disease Control and Plant Health, dated March 4, 2008
Exhibit C-5	E-mail from BASF to EPA, dated November 13, 2008
Exhibit C-6	Letter from EPA to BASF re Supplemental Label, dated January 23, 2009
Exhibit C-7	Letter from Universities re Pyraclostrobin (Headline) Supplemental Label, dated February 13, 2009
Exhibit C-8	E-mail from EPA to BASF, dated March 3, 2009
Exhibit C-9	Summary of BASF and EPA Meeting, dated November 14, 2013
Exhibit C-10	*In the Matter of BASF Corporation v. Willowood USA LLC,* No 01-16-0000-7029 (July 6, 2018).
Exhibit D	EPA Product Performance Test Guidelines, dated March 1998
Exhibit E	Pyraclostrobin Preliminary Work Plan, dated June 2014
Exhibit F	Transmittal Document, dated March 30, 2015
Exhibit G	EPA Memorandum re Review of Honey Bee Queen Study, dated May 15, 2013
Exhibit H	Generic Data Call-In, published October 20, 2015
Exhibit I	Specific Data Call-In, dated October 20, 2015
Exhibit J	S. Bradbury (EPA) Clothianidin Response Letter, dated February 18, 2011

Exhibit K	Ecological Risk Assessment, dated February 4, 2011
Exhibit L	EPA Meeting Summary, dated March 29, 2005
Exhibit M	Sharda Cite-all Offer to Pay Letter to BASF for Sharda Pyraclostrobin 20% WG, dated June 11, 2021
Exhibit N	Letter to EPA, dated January 2014
Exhibit O	EPA Letter to BASF, dated February 6, 2015